Pesticide Program Dialogue Committee PRIA Process Improvement Workgroup

Minutes of the April 29, 2008, Meeting

Workgroup Members Attending:

Kevin Costello, Special Review and Reregistration Division (SRRD), Office of Pesticide Programs (OPP)
Sue Crescenzi, Steptoe and Johnson on behalf of the American Chemistry Council Biocides Panel
Susan Ferenc, Chemical Producers and Distributors Association (CSPA)
Ted Head, NuFarm
David Jones, Nice-Pak on behalf of International Sanitary Supply Association (ISSA)
Jim Kunstman, PBI/Gordon
Beth Law, substituting for Phil Klein, Consumer Specialty Producers Association (CSPA)
Elizabeth Leovey, OPP
William McCormack, Clorox on behalf of CSPA
Marty Monell, OPP
Amy Roberts, TSG on behalf of BioPesticide Industry Alliance (BPIA)
Julie Schlekau, MGK on behalf of Responsible Industry for a Sound Environment (RISE)
Julie Spagnoli, FMC on behalf of the Pesticide Program Dialogue Committee (PPDC)
Greg Watson, Syngenta on behalf of CropLife America (CLA)
Mae Wu, Natural Resources Defense Counsel (NRDC)

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Minutes

Introductions

After participants introduced themselves, Marty Monell, Deputy Director of Program Management, Office of Pesticide Programs (OPP) began the meeting by reminding participants of the statutory provision on process improvement in both the Pesticide Registration Improvement Act (PRIA 1) and the Pesticide Registration Improvement Renewal Act (PRIA 2) and the recommendation of the Pesticide Program Dialogue Committee (PPDC) that this workgroup be formed to provide a public forum in which to discuss process improvements in EPA's registration program. Under PRIA 2, PRIA was reauthorized for another five years and the statutory provision on the PRIA annual report was expanded to include a yearly report by EPA on its recommendations for process improvements in the handling of registration review and in streamlining the registration review process. To provide a public forum in which to discuss these improvements, registration review will be a topic of the workgroup as of this meeting.

External Review of Product Reregistration

Following a reregistration decision, the Agency reregisters each individual product associated with the reregistration action. Registration review, registration of a pesticide every 15 years, is being implemented while the Agency completes product reregistration. Process improvements in product reregistration will allow more Agency resources to be devoted to registration review. The Agency's Office of Policy, Economics and Innovation sponsored an external review of the product reregistration process which was conducted by Abt Associates. Their findings of March 30, 2007 were described by Peter Caulkins, Associate Director, Special Review and Reregistration Division (SRRD)

The purpose of this external review was to identify potential opportunities to streamline the product reregistration process, to increase its efficiency and to ensure timelier implementation of mitigation required in a Registration Eligibility Document (RED). Of the universe of approximately 20,000 products, 40% (8,792) had completed product reregistration while 60% (13,245) remained to be completed as of this meeting. Of the 8,792 completed, 2,853 were reregistered without changes, 678 were amended to address one of the active ingredients in the product, 5,255 were cancelled, and six were suspended.

Initially, an analysis was conducted of how long it took the Agency to complete reregistration of an active ingredient's products. The mean duration to complete reregistration of all products associated with a RED at the end of FY 2006 reported in the external review was 54 months. It took SRRD 40 months from completion and sign-off of a RED to batch the products into study requirement groups, to obtain Office of Management and Budget (OMB) approval and then issue the Data Call In (DCI) for the required studies, for data to be generated and submitted, and for the Agency to review the data and labels and prepare the reregistation package for the Registration Division (RD). The Registration Division's Product Managers took an average of 14 months to complete label review and to reregister the products. The amount of time required to register all of the products associated with a RED was not a function of the number of products associated with a RED.

Of the products pending reregistration in FY06, 71.4% were associated with REDs signed in 2006, 9.7% with those signed in 2005, 13.6% with those from 2000-2004 and 5.2% with those signed prior to 2000. Delays were due to post-RED issues that included unresolved issues identified in a RED, review of rebuttals and additional information submitted during the stakeholder process, delays in registrants generating new data, issues identified after the RED had been signed such as inconsistent or missing mitigation measures, and the Agency's priority to devote its resources to meeting statutory tolerance reassessment and reregistration deadlines. Another source of the delay was the lengthy DCI justification process which changed over time from requiring approval for only costly studies to most studies and a review process that involves a number of divisions within OPP and RCS, USDA and OMB. The report observed that justifications for why a study should be conducted were not part of a RED and were developed after the RED had been signed and on an ad hoc basis, and that there was a large backlog of these justifications. In response to these findings, justifications are currently being developed with the REDs and a committee devoted to justifications had substantially reduced this backlog.

A report finding was that there was a duplication of effort between SRRD and RD in reviewing labels. To reduce it, a streamlining effort was undertaken by these two OPP divisions that began with a pilot involving 2,4-D products in which similar products were batched or grouped relative to the data required to support them. As a result of this effort, for 2,4-D's 603 products, only 1,027 acute tox studies were required out of a possible 3,618. This represented a 50% reduction in the amount of data to be generated and then reviewed. This effort was further facilitated by the 2,4–D registrants forming a task force so that the Agency communicated with the 2,4-D Task Force and not individual companies. The members of the Task Force furthermore resolved data compensation issues that reduced the number of studies to be conducted. Similar batching efforts are being implemented for other chemicals that have Task Forces.

This streamlining effort resulted in process changes. To avoid losing information and the additional burden of staff becoming reacquainted with a chemical when information is forward between organizations sporadically, a product reregistration package is

forwarded from SRRD to RD only when it is 95% to 100% completed. Furthermore, packages contain only final data reviews, the Confidential Statement of Formula (CSF) and labels with any other information placed in the chemical file (jacket). This other information includes SRRD's correspondence with the registrant in resolving data and mitigation issues. SRRD is also sending personnel to help RD when necessary. RD in turn completed a mitigation pilot in which mitigation was placed on a label prior to completing product reregistration. By expediting mitigation, protection of human health and the environment does not wait until product reregistration is completed. The amount of time required to place the required mitigation language on the pilot chemical's labels was 5 to 8 months.

The external review recommended improved transition of REDs from SRRD's reregistration branches to its Product Reregistation Branch (PRB), greater participation by RD in developing label tables to enhance quality, consistency and appropriateness of label language and early mitigation when cost-effective and based on the level of mitigation required by the RED. The external review furthermore recommended that electronic labels be pursued to streamline the label review process, and that additional regulatory action should be taken when registrants are in non-compliance which may include cancellation or suspension of products. Regarding the DCI process, additional findings were that DCI justifications should be thorough to avoid delays due to resubmissions to OMB, that the risk assessment formats should contain rationales for each study required and that additional science support be allocated for the DCI justification process.

Additional recommendations included expanding the batching process with other industry task forces, retaining the review of acute tox and product chemistry data within PRB while continuing the label review conducted by RD, conducting meetings between RD and SRRD when final review packages are sent to RD, and allocating additional resources to product reregistration to complete it in 2014 rather than the projected 2018. To reduce backlogs, the use of SWAT teams and other strategies such as SRRD staff helping RD staff and incorporating quantitative performance goals into staff and managers' performance standards were recommended. PRISM should contain the functionality to enable tracking and reporting on each component of the product registration process, internal and external communication of product reregistration needed to be enhanced, and the Web site should be used to maintain a repository of reregistration decisions including any amendments to REDs. In responding to the accountability recommendations, the Deputy Office Director of the Pesticides Program holds monthly meetings to assess progress in meeting product reregistration goals stated in its managers' performance standards.

A summary of the Abt report is available on www.epa.gov/evaluate/reports.htm [scroll down to OPPTS]. In response to a question, a link will be provided to the summary on the pesticides Web site.

In response to questions, Mr. Caulkins advised registrants to contact SRRD when rebuttals are submitted in response to use restrictions placed on the label during product

reregistration and when the registrant is concerned with their state registrations. Ms. Spagnoli inquired whether registration review's docket process is an improvement over the RED process in which information was being received continuously throughout the assessment and public processes. Mr. Caulkins commented that it was too early in the registration review effort to determine whether the docket process is working as predicted in assuring that all relevant information on an active ingredient is available at the beginning of the reassessment process.

Because of the large amount of data to be developed for product reregistration and limited lab capacity, a workgroup member asked whether more in vitro tests will be accepted. Ms. Monell responded that it is under discussion and Mr. Caulkins commented that since there is a limit on the amount of the Agency's resources, due dates are expected to be staggered which may reduce the pressure on lab capacity.

In response to a question as to whether a similar review will be conducted of the Antimicrobial Division (AD) and the Biopesticide and Pollution Prevention Division's (BPPD's) product reregistration processes, Michael Hardy, AD responded that such a review of AD has not been discussed and in general AD expects to be able to complete product reregistration as expected with the help of e-label review and contractors, though due dates will be staggered. E-label review is currently voluntary, however, the Agency may look into the possibility of requiring an electronic label during the DCI process due to the savings in time when labels are reviewed electronically. According to Leonard Cole, a BPPD external review is not planned. The Division has only 16 products to reregister.

Concerning questions on product batching and efficacy study requirements, Mr. Caulkins mentioned that once DCIs have been approved, SRRD will consider how to conduct a batching process for efficacy studies. Past batching efforts focused on acute tox studies.

A workgroup member suggested than an electronic master label could be one means to determine whether mitigation was being placed on a label as described in the RED.

PRIA 2 Implementation

Primary/Secondary and Other PIRA 2 Implementation Issues

Updates to the PRIA 2 Web site (http://www.epa.gov/pesticides/fees/), payment procedures, the fee category interpretations and primary/secondary applications were presented by Elizabeth Leovey, Senior Advisor for PRIA Implementation, OPP. The PRIA 2 Web site was updated with pages on applying for and processing IR-4 exemptions (http://www.epa.gov/pesticides/fees/questions/guidance_ir-4.htm) and on the 21 Day Initial Content Review Worksheet (http://www.epa.gov/pesticides/fees/questions/pira21day-screen.htm). Updates are expected to the 21 Day Initial Content Review Worksheet and the inerts pages and will include incorporating the revised fee category interpretations on the Fee Determination

Decision Tree (http://www.epa.gov/pesticides/fees/tool/index.htm). As information becomes available, it is posted on this site.

Since only a small percentage of applications are being received without payment, pre-payment and the Fee Determination Decision Tree are being effectively utilized. Participants were reminded that there are three pesticide payment forms on pay.gov (https://www.pay.gov/paygov/) specifically for pre-payment, payment following an invoice from the Agency and maintenance fees. The appropriate payment form must be used to assure that the Agency can match a payment with an application. For the same reason, the company number must be on a check. If paying by check, each application must be paid separately. Combining payments has led to tracking issues.

A draft of the revised fee category interpretations was circulated internally within the Agency and will be made available to the PRIA Coalition for comment. Once finalized, the interpretations are expected to be placed on the Fee Determination Decision Tree. Issues being resolved include the definition of a food use and the interpretation of the refined ecological risk/endangered species assessment fee categories.

Pesticide registration applicants periodically submit multiple applications that are linked in some manner, for instance, they all depend upon a common data set. Under PRIA 1, these situations were termed "parent/child" and the fee for the "child" was reduced to reflect the decreased amount of work that the Agency had to perform for the child. In the case of a new active ingredient or first food use, the "children" were included in the fee. Under PRIA 2, the Agency is limited in the amount that it can reduce a fee. Following an examination of its practices and policies under PRIA 1, the Agency developed a draft document on fee reductions for multiple applications. To differentiate it from PRIA 1, the relationship between applications is being termed "primary/secondary". The draft document was made available to the PRIA Coalition for comment. Once finalized, the document will be posted on the PRIA 2 Web site.

In general, all uses, products and petitions submitted with an application to register a new active ingredient or first food use are included in the fee. All label amendments associated with an application to register a new use are included in the new use fee. A separate table was developed to list fee reductions when multiple new products were submitted that depended upon the same data. Label amendments associated with a tolerance petition to increase or decrease a tolerance are included in the fee for R292, R295 and R296. There is a single label amendment fee if the same label amendment applies to a number of labels and all label amendments are submitted at the same time.

Bill McCormack will send his suggestion to the Agency on options that allow a Fee Determination Decision Tree user to easily identify when a fee does not need to be paid. Ms. Leovey mentioned that when the Decision Tree is updated with the revised fee interpretations, the decision review period timeframes will be incorporated. Karen Warkentien, Lewis & Harrison, inquired about the documentation required to demonstrate offers to pay. Linda Arrington, RD, responded that such documentation consists of copies of the letters of authorization. Copies of the letters of authorization are

critical in assigning certain fee categories. Specifically, R300 and A530 require such documentation whereas a R301 and A531 do not.

In response to Jim Kunstman's question on refunds, refund requests should be sent to the RD ombudsman for R categories according to Linda Arrington, RD and to the Product Manager for A categories according to Michael Hardy, AD. Mr. Kunstman also suggested that the Agency's acknowledgement of payments and receipt of applications contain both the pay.gov tracking number and decision numbers to enable registrants to link them.

21 Day Initial Content Review Screen

The status of the 21 day initial content review was described by Elizabeth Leovey, Michael Hardy, Antimicrobial Division, Leonard Cole, Biopesticides and Pollution Prevention Division and Linda Arrington, Registration Division. Under PRIA 2, EPA has 21 days after it receives the application and the fee to determine whether the full fee has been paid or a portion paid with a fee waiver request for the remainder with the application and whether the application contains all of the necessary forms, data, and draft labeling, formatted in accordance with guidance published by EPA. If the application does not pass the initial screen and cannot be corrected within the 21 day period, EPA is to reject the application not later than 10 days after making the determination. The Agency's planned procedures were described during a November, 2007 PRIA 2 workshop (http://www.epa.gov/pesticides/fees/pria2workshop1107/index.htm) and the content screen was phased in at the beginning of January 2008.

As of this meeting, five applications had been rejected (one antimicrobial, one biopesticide and three conventional applications). The screening worksheet had been posted on the Agency's Web site with links to the appropriate forms and guidance. Two issues are still being discussed within the Agency, whether documentation of offers to pay had to accompany the application and if applications other than new active ingredient, first food use, and conventional new product-inert approval applications will be rejected for unapproved inerts. The regulatory divisions are conducting the screen and the Agency expects to begin using a contractor to conduct both the Pesticide Registration Notice 86-5 and 21 Day Initial content screen in September 2008. The experience gained by the regulatory divisions in conducting the screen will be used to train the contractors and regulatory divisions are monitoring which forms, documents or data present the most problem for registrants.

Michael Hardy reported that the Antimicrobial Division had modified its procedure since the November workshop. The team assigning PRIA fee categories is also conducting the initial content review using the review worksheet and is generally completing the screen and forwarding the screening worksheet to the PM within a couple of days of receipt. The status of inerts and cited products are determined and existing uses compared with proposed uses. Once the initial content review is completed, the product manager completes the data screen and makes a least two attempts to contact the applicant

concerning missing information and/or data. PRIA applications and potential rejections are discussed within AD on Tuesday and Thursdays and with AD management on Wednesdays. Rejection letters are concurred upon by AD management with final approval by the Office Director or designee. If deficiencies are identified after the 21 day content screen has been completed and 21 days have elapsed, a 75 day deficiency notice per 40 CFR 152.105 will be issued.

The Antimicrobial Division observed that among the applications screened to date, over half to 70% were missing a form or had 86-5 errors that were corrected after the applicant was contacted and within the 21 days. In general, PRIA submissions have improved and if there were problems, they concerned the data matrix and/or the CSF, for instance, improper use of the formulator's exemption, and unapproved inerts. In the future, AD will meet with stakeholders to resolve issues related to product chemistry and will post a list of current data requirements by use site on its Web site. Mr. Hardy encouraged pre-submission meetings between an applicant and the Agency since the better submissions were those that followed a pre-submission conference.

Leonard Cole noted that the Biopesticides and Pollution Prevention Division had observed an improvement in the applications reviewed by the Division and that many of the difficulties were a result of not following the 86-5 guidance. During the first quarter of FY08, BPPD received 19 PRIA applications, 10 had 86-5 issues, and 3 had content issues. All but one was corrected within the 21 day period. In the second quarter, 37 were received, 11 had 86-5 issues, and none had missing contents and all 11 were corrected within the 21 day screening period. During the first two weeks of the third quarter, 3 were received, one had 86-5 issues, and none had content issues.

Linda Arrington reported that the Registration Division had screened 336 PRIA actions. Based on a sample of 43, the most common errors were inerts not approved for the proposed use and missing or incorrect data certification statements. Reasons why three conventional applications were rejected included incomplete data matrix, CSF and/or formulator's exemption, 86-5 issues, missing required data and data matrix, and a refusal to submit information on the contents of an inert mixture. Common errors included inerts not approved for the intended use, studies not formatted following 86-5, missing or incomplete data matrices and missing or incorrect certifications with respect to the citation of data. The Registration Division has made an effort to forward 86-5 corrections as soon as possible after receipt to the 86-5 screening contractor so that corrections can be resolved within the 21 day period. The number of unapproved inerts decreased after the approved inerts lists were posted on EPA's inerts Web site.

In response to Amy Robert's question, once retained, the same contractor will be conducting the 21 day content screen for all three registering divisions. She suggested that applicants be sent a notice when their application has successfully completed the content screen and since 86-5 issues continue to be a problem, that the Agency develop checklists and possibly reissue the FR Notice. Ms. Leovey commented that EPA has formed an 86-5 workgroup and any suggestions on improving 86-5 should be forwarded to Steve Robbins, the workgroup chair.

In response to a question on what will happen if an application's inert is not approved for the intended uses, Ms. Arrington responded that the Agency will work with the applicant to find an appropriate alternative which will not require new product chemistry data. If this is not possible, the application is generally withdrawn.

Ms. Spagnoli reported that registrants call product managers to obtain their PRIA due dates and suggested that the Agency notify the applicant of the date. In response, EPA's tracking system would need to be modified and once higher priority modifications and enhancement have been completed, the Agency will develop the necessary system enhancements.

Updates on Topics from Past Workgroup Meetings

Notifications Reviewed by the Registration Division

Linda Arrington, PRIA Ombudsman, Registration Division and RD Notifications Team Leader summarized the status of notifications processed by RD. During the period from October 1, 2007 to April 15, 2008, the Division completed 949 notifications of which 831 were labeling and CSF notifications and 118 were minor formulation amendments. The average number of days to completion were 36 and 56, respectively. During the same period, 334 of the backlogged actions were completed and consisted of 294 labeling and CSF notifications and 40 minor formulation amendments. The average number of days to complete these actions was 63 and 85 days, respectively. As of April 14, 2008, 682 notifications were pending of which 523 were backlogged actions and were 544 labeling and CSF notifications and 138 minor formulation amendments. To help process the increase in the notifications resulting from Pesticide Registration Notice (PRN) 2007-4, the division added two individuals to the team. During FY08 and as of this meeting, 158 of these notifications had been completed and 139 were pending with more expected.

Ms. Arrington suggested that if applicants had questions about the status of their notifications in the backlog, they should contact her. Applicants should also contact her if they would like to withdraw a notification because they would like to submit an amendment instead.

Inerts

Current activities of the Inert Ingredient Assessment Branch (IIAB) were reported by P.V. Shah, Acting Branch Chief, Registration Division. To date during FY08, IIAB had substantially reduced its petition backlog to five submitted prior to FY08. It had granted 8 food-use petitions and approved 11 non-food use inerts. Fourteen food-use petitions were expected to be withdrawn and 3 were denied due to insufficient data. The inerts Web site (http://www.epa.gov/opprd001/inerts/lists.html) was updated with a list of approved inert ingredients on December 19, 2007. Specifically, the non-food list was updated, the 25(b) list was consolidated and links provided to the e-CFR for locating food-use tolerance exemptions, and to USDA's National Organic Program list.

Under PRIA 2, there are fee categories for conventional new product applications with inert approval requests. Two food-use petitions were received in conjunction with PRIA 2 new product applications. One application is undergoing correction as a result of the 21 day initial content screen. Mr. Shah encouraged applicants to contact IIAB with their questions before and while they develop their application to clarify what needs to be submitted.

On August 9, 2008, 123 inert tolerance exemptions will expire due to insufficient data required to assess their risks. The Agency published a Federal Register Notice on November 2, 2007 listing the 62 inerts for which industry, specifically the Joint Inert Ingredient Task Force, expects to submit supporting data and listing the 61 which will not be supported. The expiration date for the supported inerts will be extended to August 9, 2009 by which time the Agency expects to have established a new tolerance for these chemicals that meet the FQPA safety standard. All data are due December 31, 2008. The Joint Ingredient Task Force provided the Agency with their schedule for developing the data and EPA is reviewing the studies already submitted by the Task Force.

Regarding the unsupported inerts, the Agency is currently identifying the pesticide products that contain these inerts. Some the Agency believes are no longer in use. Registrants will be given the option of reformulating a product or canceling it. After August 9, 2008, a food use product will not be registered if it contains an inert with a revoked exemption.

As previously reported, IIAB reviews CSFs for unapproved inerts and the Product Manager is contacted to work with the applicant in correcting any problem. All inerts must be approved for the use when a new product is registered. "Stand alone" inert submissions, not tied to a new product application, are also screened and only complete submissions are placed on the inerts workplan. Submitters are informed within two to three weeks as to whether their submission is adequate. In general, the chemical name, CAS Reg. No. and the requested uses must be clearly stated and sufficient data and information submitted for an action to be complete. The Branch expects to issue guidance on the data and information to be submitted in an inert ingredient request.

Under the Food Quality Protection Act, food use inert ingredients are covered by the data compensation regulations. The Agency is in the process of developing an Inert Ingredient Submitters List. The initial list is expected to be made available to stakeholders for review and comment. An Advance Notice of Proposed Rulemaking on data compensation is expected by the end of 2008. The pesticides program is coordinating with the Endocrine Disruption program to ensure that data compensation provisions will be compatible. In the interim, internal procedures for implementation of data compensation have been established.

The Fragrance pilot mentioned in previous workgroup meetings was expected to be extended to antimicrobial products. The purpose of the pilot was to determine whether a notification programs would be appropriate for approving fragrance inerts. To qualify

for the subsequent provisional notifications process, the inert has to be on the list of fragrance components on IIAB's Web site (http://www.epa.gov/opprd001/inerts/) and meet the criteria of the Fragrance pilot. As of April 2008, the list contains approximately 1,530 compounds. The Fragrance Manufacturers Association is submitting data to support these chemicals and the Agency is in the process of reviewing the data and conducting risk assessments. Approval of chemicals not listed on the Web site must follow the same procedure as a non-food use inert ingredient.

As previously mentioned, the CFR is in the process of being revised and CAS numbers added to tolerance exemptions to allow on-line searches by CAS number. The EPA anticipates an easy and rapid process for adding CAS numbers to existing tolerance expressions and will publish a process in the Federal Register for public comment, tentatively scheduled for summer 2008. A number of errors have already been identified by industry. Internally, EPA is in the process of modifying its tracking systems to track and monitor all requests to approve new inerts.

In response to questions, inert suppliers should be contacted to identify the contents of a mixture prior to submitting an inert action that involves an inert mixture. Ms. Roberts encouraged the Agency to work with USDA on a list of inerts for the organics program since the "old" inerts lists have disappeared and inerts are currently classified as only food or non-food use. Ms. Monell indicated that the pesticide program will follow up on her concern. Greg Watson on behalf of the Inert Steering Committee informed the workgroup that the Committee will be submitting a model and suggestions to the Agency in a couple of weeks on adding CAS numbers to the CSF.

Quality Improvement Workgroup and Product Chemistry

Tyrone Aiken, Registration Division described three quality improvement initiatives being undertaken by EPA. The Quality Improvement Workgroup composed of representatives from all OPP divisions is focusing on frequently asked questions and answers and making information easy to find, understand and use by the general public. By using the Enterprise Customer Service System (ECSS), questions and answers may be searched on the Web which should reduce the number of calls and e-mails received by staff and allow more time for other activities. Ms. Monell following this presentation, encouraged the meeting's participants to access the EPA's Web page and the "Frequently Asked Questions" Web site, to try the software, and to forward any suggestions to Mr. Aiken. The program expects to have the pesticide questions and answers available in a couple of months following this meeting and suggestions will be used in developing it. Once in operation, usage will be monitored to further improve the site.

To help improve registration applications, Mr. Aiken reported that a registration tutorial Web page is being developed to help applicants avoid common errors with an emphasis on product chemistry, inerts and CSFs. As part of this effort, the product chemistry and CSF tips currently on EPA's Web site will be consolidated.

A prototype of an electronic CSF has been tested and its systems requirements are currently being developed. The prototype featured drop down lists, corrected math errors and provided hints on completing a CSF.

Labeling

The Process Improvement Workgroup was updated by Elizabeth Leovey, OPP, on the activities of the OPP Labeling Committee and on other labeling projects within the pesticides program initiated since the September 27, 2008 meeting. The OPP Labeling Committee, as described in past meetings serves as a clearing house for broad cross-cutting label issues, manages a Web site devoted to labeling issues and revises and keeps the Label Review Manual (LRM) current. As of April 10, 2008, the Committee had received 175 questions on its Web site (http://www.epa.gov/pesticides/regulating/labels/label_review.htm) and e-mail box (http://www.epa.gov/pesticides/regulating/labels/label_review_faq.htm) , had answered 165, had posted 100 and is in the process in addressing 10. New items are flagged as "new" for 30 days and the date that a question is completed by the Committee is shown by each answer. A disclaimer on the site states that the answers do not create new guidance. Revisions to the site are expected in the future.

The Committee's subgroup, the LRM Team, had updated eleven chapters of the Label Review Manuel (http://www.epa.gov/oppfead1/labeling/lrm/) , two are being reviewed by the Labeling Committee and the last six chapters are being drafted with a target date for completion by the end of 2008. The Environmental Hazard General Labeling Statements on Outdoor Residential Use Products is being finalized and comments are being analyzed for the PR Notice on Third Party Endorsements and Cause Marketing Claims.

The pesticides program initiated two other labeling projects since the last meeting. A Label Accountability Workgroup (LAW) was formed in response to concerns by the Regional offices and States that some labels are difficult to enforce. The workgroup is composed of representatives from the program, enforcement, Office of General Counsel, EPA regional offices and two States. After an examination of problematic labels, the workgroup concluded that label defects could result in increased risk and incidents, undermined enforcement and were a continuous burden to EPA and the States in interpreting and/or rectifying deficient labels. The workgroup recommended that training materials be developed for label reviewers, that a quality assurance process be developed and tested, that the State Labeling Information Tracking System (SLITS) and other mechanisms be used to provide feedback as to whether problems are being corrected and that for the long term, Web based labeling be developed. The pesticide program is proceeding with developing guidance, training and the quality assurance program. Participants were encouraged to contact Jim Roelofs (roelofs.jim@epa.gov, 703-308-2964) for any questions and suggestions on the LAW.

The other labeling effort is Web-based distribution labeling (http://www.epa.gov/pesticides/regulating/labels/distribution/index.htm) which will be

described and discussed during the May 21, 2008 PPDC meeting by William (Bill) Jordan (jordan.william@epa.gov). Web-based labeling is envisioned to be a system which would make the most current version of a pesticide label available to purchasers and users electronically on an EPA-maintained Web site.

Greg Watson and Sue Crescenzi mentioned that the registrant community would benefit from guidance being provided to the States on SLITS.

Electronic Submission

After a successful electronic submission pilot described during the September 27, 2008 meeting of the Workgroup, e-submission will be implemented and Oscar Morales, Director, Information Technology and Resources Management Division (ITRMD), updated the Workgroup on its implementation schedule. He announced that based on the pesticide program's experience with the pilot, the PRISM e-submission/Documentum module is expected to be launched summer 2008. It is one step in the Office of Pesticide Program's efforts to move towards a paperless work environment. Once e-submission is implemented, any paper received by the program will be scanned and stored in Documentum and used electronically. Benefits to industry of electronic submission include paper reduction and an ability to submit to multiple regulatory agencies. The Agency anticipates efficiency improvements due to a reduction in transcription errors and the ability for concurrent review of documents which will allow additional time to review submissions.

E-submission is a new process for the pesticide programs. During the initial phase of e-submission, applications involving Section 3, Experimental Use Permits, tolerance petitions and distributor products may be submitted to EPA on CD or DVD or a combination of paper and electronic media. Guidance is available on formatting the CD or DVD. As of May 5th a help desk will be available to answer questions and the telephone number will be published (Toll Free: 1-866-612-8664 Local: 703-326-0673 or by email OPPeSubmissionHelpdesk@epa.gov). The PRISM e-submission model leverages the XML and packaging format found in Pest Management Regulatory Agency, Canada's e-index builder. The system provides an ability to separate an incoming package into data and attachments, to perform some "error checking" and to move data and attachments to other PRISM components for further processing. In the future, OECD templates will be incorporated to facilitate global work sharing and harmonization.

A live demonstration of both the e-submission and Documentum applications were performed. Dominique Rey-Carruth, ITRMD, demonstrated the steps involved in the Agency's receipt of an e-submission and its transfer to Documentum. Ben Cobb, ITRMD then demonstrated and discussed how Agency staff would use a document in Documentum.

In response to a question on how a registrant would know that a package was in review, Ms. Rey-Carruth mentioned that when a pay.gov payment and electronic submission are matched and a "Decision" created, the applicant is sent an acknowledgement of receipt.

After e-submission is implemented, Product Managers will be notified by the system when documents are available for review and documents will be designated as draft until the 86-5 review has been completed.

The workflow component of the system will be installed in the latter portion of calendar year 2008 according to Mr. Morales. This component will allow documents to be transferred within the program. Until installation, documents will be accumulated into a library.

Ms. Monell mentioned that e-submission and use of Documentum will be a cultural change for program staff as demonstrated by the implementation of e-label review. E-submission is a substantially larger effort and will be a challenge for both the Agency and applicants.

In response to a question from Amy Roberts, submissions built with PMRA's e-index builder can be submitted though additional fields need to be developed for the US submission as described in the guidance. Prior to the meeting, ITRMD held a conference with OECD in which common transport mechanisms were discussed that would allow applications and documents to be electronically submitted and transferred between multiple regulatory agencies to facilitate global joint reviews and work sharing.

Bill McCormack suggested that the Agency assure that electronic systems are secure particularly any system that contains approved labels such as Pesticide Product Labeling System (PPLS). Greg Watson reminded participants of an initial PRIA Process Improvement priority of automated communication to registrants of completed milestones during the registration process. Ms. Monell commented that the automated notification system is on the Agency's list of systems improvements. In response to a question on whether the regulation specifying the number of paper copies is being re-considered, Ms. Monell reported that any change in the regulation (40 CFR 152.5 and 40 CFR 158.32(b)(3)) will require rule making and is currently being addressed.

Electronic Label Review

Marty Monell reminded participants that electronic label review is a priority for the Agency and that instructions need to be followed in naming e-label files to assure that EPA can receive and review them. Registrants were encouraged to submit more e-labels so that EPA staff will gain experience with and acceptance of the methodology.

Ms. Spagnoli mentioned that issues concerning "accepted with comments" need to be addressed. Ms. Monell reported that the Agency is addressing the concern as discussed during a meeting with the PRIA Coalition. According to Dennis Howard, Florida Department of Agriculture, the States need assurance of the integrity of the PPLS and timelier posting of stamped labels. Mr. Morales responded that ITRMD is addressing the need for prompt posting of stamped labels on PPLS in response to comments that States are becoming more dependent upon PPLS to determine whether EPA has approved a label and in response to a recent enforcement case.

Public Comments

No public comments were received.

Preparation for Next PPDC Meeting and Meeting of the Workgroup

Ms. Monell announced that during the May 20-21, 2008 PPDC meeting, many of the issues presented during this meeting will also be discussed. For the Workgroup's update to the PPDC, Elizabeth Leovey will report on activities that will not be covered during the rest of the PPDC meeting and discuss the Workgroup's successes. She thanked participants for attending and announced that the next meeting will be held fall 2008.